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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/327,761	06/07/1999	DONALD W. PETERSEN	99.501	5876

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EXAMINER	
WITZ, JEAN C	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/327,761	PETERSEN ET AL.	
	Examiner	Art Unit	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,12-21 and 35-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,12-21 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1104*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 22, 2004 has been entered.

Response to Arguments

Applicant's arguments filed November 22, 2004 have been fully considered but they are not persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-3, 12-21 and 35-38 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of O'Leary et al. (5,484,601), Yim et al. (5,385,887) and Gertzman et al. (6,030,635) taken as a whole for the reasons of record.

Applicants continue to argue that Gertzman teaches away from the composition of O'Leary by pointing out the discussions in Gertzman which address issues with a composition identified in Gertzman as GRAFTON® and is described as a "simple mixture of glycerol and lyophilized, demineralized bone powder of a particle size in the range of 0.1 cm to 1.2 cm." Applicants assert that the teaching of Gertzman that GRAFTON® has been "runny" when placed in vivo, as well as discussions in Gertzman about the potential toxicity of glycerol is sufficient to teach away from the disclosure of O'Leary et al. However, review of col. 2, lines 40-55, shows that Gertzman states that GRAFTON®

> "works well to allow the surgeon to place the allograft bone material at the site. However, the carrier, glycerol has a very low molecular weight (92 Daltons) and is very soluble in water, the primary component of the blood which flows at the surgical site. Glycerol also experiences a marked reduction in viscosity when its temperature rises from room temperature (typically 22 C in an operating room) to the temperature of the patient's tissue, typically 37 C. This combination of high water solubility and reduced viscosity causes the allograft bone material to be "runny" and to flow away from the site almost immediately after placement; this prevents the proper retention of the bone within the site as carefully placed by the surgeon."

This "teaching away" appears to be limited to the use of glycerol.

O'Leary et al., at col. 3, discusses the characteristics desired for a "flowable" composition. O'Leary then states at col. 35, lines 35-39 that "Suitable carriers for the bone powder include liquid polyhydroxy compounds and their esters, polysaccharides, surface active agents, and the like, the polyhydroxy compounds being preferred." Therefore, these is no requirement in the teaching of O'Leary that glycerol, while disclosed as preferred, is the only embodiment contemplated in the practice of the invention of O'Leary. The teaching of a U.S. patent is not limited to the preferred

embodiments and per Merck & Co., Inc. v. Biocraft Laboratories, Inc., 10 USPQ2d 1843 (CAFC 1989), the fact that a specific embodiment is taught to be preferred is not controlling and the mere absence from prior art of teaching or limitation recited in claims at issue is insufficient for finding of non-obviousness. The cellulosic plasticizing agents of Applicants' invention are, in fact, polysaccharides. The patent to Gertzman shows that malleable pastes are preferred in treating bone defects and that numerous substances are well known to be included in compositions for treating bone defects such as autologous bone, allograft bone, bone marrow and blood.

With regard to the O'Leary patent, Applicants continue to argue that the term "inorganic elements" disclosed in the O'Leary patent do not and cannot be referring to calcium salts such as calcium sulfate. As stated in the previous office action, the Examiner acknowledges that the disclosure of O'Leary does not explicitly disclose the inclusion of calcium sulfate; however, O'Leary teaches that "any variety of substances" may be included in the composition, including what O'Leary describes as "inorganic elements." Also as stated previously, such an interpretation of O'Leary is too narrow. Terms in both specifications, claims and in the prior art patents are given their broadest reasonable interpretation consistent with the specification. There is nothing in the O'Leary specification that specifically states that calcium salts and specifically calcium sulfate is not intended to be included. In fact, since the composition of O'Leary is specifically designed to be implanted for bone repair and since bone tissue is composed to a great degree of inorganic elements such as calcium, it would be expected that broadest reasonable interpretation of the term "inorganic elements" included sources of

calcium. Further, it remains unclear how the inorganic elements of O'Leary would be expected to have a bioactive effect yet the calcium sulfate, clearly inorganic, would not have a similar bioactive effect. Bone is composed of both organic and inorganic components and calcium is deposited in inorganic form in bone tissue to provide a hardening effect to the bone tissue so that the bone tissue can provide the required support for the organism. It is not seen how this effect is anything other than bioactive. Also, at the time the invention was made, one of ordinary skill in the art would have been aware that the calcium sulfate hemihydrate would eventually be resorbed, and the calcium contained therein would be used to replace the calcium sulfate hemihydrate with bone tissue. Again, it remains unclear how this effect is not "bioactive".

Finally, Applicants assert that the teaching of the Yim reference must be limited to a suggestion to combine a calcium sulfate hemihydrate-containing substance (CSHS) with the formulation of U.S. Patent 5,171,579 which is a formulation of osteogenic proteins, a blood clot and a porous particulate polymer matrix. This is merely one embodiment of the disclosure of Yim and Applicants' assertion fails to address, for example, the statement found at col. 2, lines 27-31, found in the Summary of the Invention section, which identifies another embodiment of the invention of Yim, specifically "[y]et another embodiment of the present invention comprises formulation of osteogenic protein and a suitable quantity of a CSHS. The formulation may optionally include other protein sequestering agents, particularly cellulosic materials." The formulation referred to by Applicants is merely one embodiment of several disclosed by the Yim patent and the teachings of a U.S. patent are not limited solely to a single or

even the preferred embodiment. Therefore, it is clear that Yim does suggest the combination of osteogenic proteins, CSHS and a cellulosic material (as defined at col. 7 and within the scope of the claimed "plasticizing substance") for repair of bone. One of ordinary skill in the art is well aware that compositions that contain osteogenic proteins include demineralized bone matrix (DBM) and that demineralized bone matrix is a common source of these proteins; in fact, this is one of the reasons why O'Leary uses DBM in his formulation, i.e. as a source of these proteins. See O'Leary at col. 1, lines 15-21. It is not seen how the disclosed benefits of inclusion of CSHS to the embodiment discussed by Applicants would not also be expected to be imparted to all of the embodiments discussed by Applicants in the Summary of the Invention, including the embodiment discussed above. Further, given that Yim's teachings suggest a composition comprising osteogenic proteins, CSHS, a cellulosic material and a mixing solution to activate the CSHS, and given that broadest reasonable interpretation of a composition that comprises osteogenic proteins includes within its scope demineralized bone matrix, the disclosure of Yim actually discloses a composition that includes three of the four components claimed by Applicants, and teaches the inclusion of components specifically derived from the fourth component. Finally, it is noted that Applicants' claims recited "open" claim language, allowing for the inclusion of other components. Therefore, Applicants' assertions regarding the Yim reference have not been found to be persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jean C. Witz
Primary Examiner
Art Unit 1651

December 10, 2004